



**Participant Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Study Title:** "Effects of Broccoli Sprout Extract on Allergic Rhinitis"

**Principal Investigator:** Zhaoping Li, MD, PhD

Phone: 310-268-3528

**Co-Principal Investigator:** Joseph Yusin, MD

Phone: 310-478-3711 x40230

## INTRODUCTION

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. Zhaoping Li, Dr. Joseph Yusin and their research team. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits to you and/or to the future population of individuals you represent.

This document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as the results of the study. You must be completely truthful with your study doctor regarding your health history, including past and present usage of both prescription and non-prescription medications. If you are not completely truthful with your study doctor you might harm yourself by participating in this study.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

Your participation in this study is voluntary. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled.

If you are a VA employee or student, your refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.

Only you can decide if you want to take part in this study. You should only make your decision after reading all the questions and answers in this form. You may talk to your family, friends and/or your family doctor to help make your decision. You can take as much time as you like to decide.

After you have read the entire form, you will be given the chance to ask any questions that you may have. When you have had the chance to ask any questions and they have been answered to your





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satisfaction, if you decide to take part, sign the pages at the end of this form to show that you agree to be part of the study. This is called "giving your consent".

Even after you have signed this study consent form you can change your mind and decide not to participate in the study. You do not have to give a reason.

## BACKGROUND AND PURPOSE

Allergic rhinitis, commonly referred to as "hay fever" is suffered by many people, especially those living in high pollutant areas, despite conventional treatment. We believe that some people who suffer from allergic rhinitis may improve their nasal health if they consume broccoli sprout extracts alone or in combination with conventional medications. The purpose of this study is to see if taking a pill which contains broccoli sprout extract (BSE) will increase the levels of natural helpful antioxidant enzymes in your nose and sinuses. Antioxidant enzymes are proteins produced by the body to protect cells against the harmful effects of chemicals such as those found in air pollution. We will also be measuring certain cells that are related to inflammation in the airway. We would like to see if taking broccoli sprout extract decreases inflammation caused by nasal exposure to grass. We propose to study the outcomes of broccoli sprout extract on allergic rhinitis alone or in combination with standard of care nasal corticosteroids

You have been invited to participate in this study because you are 18 years of age or older and you may be allergic to grass.

## DURATION OF THE RESEARCH

The study is intended to recruit 475 people with the expectation of having 152 people complete the study. Your participation in this study could last up to 55 days.

## STUDY PROCEDURES

**Overview:** If you agree to take part in the study, and you qualify to continue the study after visit 1, you will be asked to come into the clinic for a total of 2 additional visits.

The study schedule is summarized in a table at the end of this section. If you qualify, it is important that you attend each scheduled visit. Visit 2 and 3 (Day 14 and 35) will last about 5 hours. We will record any possible side effects throughout the entire study.

After you have consented by signing this form, the study team will ask you about the medications that you're currently taking (including over-the-counter medications). If certain allergy medications are prescribed to you (such as loratadine, cetirizine, fluticasone, triamcinolone, etc.) we'll confirm with you the date that you last took these medications, and ask that you hold certain allergy medications during



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your participation in the study. After you and the research team have gone over your medications you will be given a list of these medications (including new vitamins and supplements) sheet to remind you to avoid taking them for the duration of the study. Three days prior to visit 1, you should avoid the following foods: arugula, bok choy, broccoli, broccoflower, brussel sprouts, cabbage, cauliflower, chard, chinese cabbage, collard greens, daikon, kale, kohlrabi, mustard greens, radishes, rutabagas, turnips and watercress. You will be given a list of these foods to remind you to avoid eating them for the duration of the study.

You will be scheduled for visit 1 within 20 days after consenting to undergo an allergy skin test that will determine if you have nasal allergies to grass pollen and will then undergo a nasal challenge test. If the nasal challenge test causes nasal symptoms (runny nose, itching, nasal congestion) you will qualify to continue with the other visits..

Once you have successfully completed the screening phase of the study, you will return for Visit 2 in two weeks.

You will need to have the following examinations, tests or procedures done during the study:

- **General Physical Examination (Day 1, 14 and 35):**

You will undergo a routine physical examination before any nasal challenge or nasal irrigation is performed. The examination will include looking into your nose, listening to your heart and lungs and obtaining your weight, height, blood pressure and heart rate.

- **Urine Test (Day 1):**

If you are a woman and can have children, a urine (and also if needed a blood) pregnancy test will be done to confirm that you are not pregnant. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.

- **Spiro metry (Day 1, 14 and 35):**

You will be asked to exhale forcefully into a tube for about 6 seconds. You will be guided by the technician. This test measures your lung function.

- **Allergy Skin Testing for sensitivity to Common Aeroallergens (Day 1):**

To determine if you will be able to participate in the entire study, we will need to determine if you have an allergy to only grass pollen. You will be skin tested to common grass pollen along with cat, dog, dust mite and mold. Allergy skin testing is a routine procedure allergists perform when evaluating patients with allergies. It involves cleaning a small area on your arm with alcohol, drying the area, then scratching the skin with a small needle containing the allergen (grass, cat, dog, dust mite or mold) on your arm we will also apply histamine and saline on your arm. After

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20 minutes, we will check the areas to see which area has a response. If you have a response it will feel like a mosquito bite with a small bump with itching and redness at the site. If you test positive to grass pollen and based on the skin test results, the study doctor determines you do not have a true allergy to cat, dog, dust mite or mold you will qualify to continue the study.

- **Nose (nasal) lavage (Day 14 and 35):**

A nose lavage is a rinsing of the nose and sinuses with a sinus rinse (sterile salt water). A nasal lavage is performed before each nasal challenge. For the nose wash you will lean over a sink with your head titled at an angle, and breathe out of your mouth while you gently pour 8 ounces (1 cup) of sinus rinse into one nostril, and let the sinus rinse drip out of the other nostril until the sinus rinse is gone.

- **Nasal Challenge (Day 1, 14 and 35):**

There will be two types of nasal challenges performed: the "up-dosing" and the "actual" nasal challenge.

The up-dosing nasal challenge completed at Visit 1: The up-dosing nasal challenge is done to determine how much grass pollen solution is needed for you to experience allergy nasal symptoms. You will need to have a certain level of symptoms in order to continue in the study. The technician will apply three sprays of the grass pollen solution into each nostril. 10 minutes after the first dose, you will fill out a questionnaire that will indicate to the technician your nasal symptom level. Based on the level of your symptoms, the technician will decide to continue the challenge with a stronger dose or to stop with that particular dose. If the technician decides to continue, you will receive one spray of a higher concentration grass pollen solution in each nostril and then complete the nasal symptom form 10 minutes following the spray. The nasal spray followed by completing the questionnaire will be repeated with gradually higher concentrations of the grass pollen solution until you experience a certain level of symptoms. You will need to have a certain level of symptoms before the technician reaches the maximum concentration. If you do not, you will not be able to continue with the study.

The actual nasal challenge completed at visits 2 and 3: The actual nasal challenge will involve spraying a grass pollen solution into both nostrils. The grass pollen concentration used will be determined by the up-dosing nasal challenge performed at the first visit. As with the up-dosing nasal challenge, you will perform a nasal lavage 30 minutes prior to beginning the nasal challenge. Over the next 4 hours, the following three items will be collected:

1. Total nasal symptom score (TNSS)
2. Peak Nasal Inspiratory Flow (PNIF)
3. Mucus collection to analyze inflammatory cells and cell markers.

Mucus collection procedure: To collect mucus, a small nasal sponge, smaller than the size of your nostril opening will be placed inside your nose, after two minutes, the sponge will be



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removed and then sent to the lab to look at the cells and cell markers. This mucus collection technique will occur at the same time intervals as the TNSS and PNIF collections 30 minutes after nasal lavage, 5, 15, 30 minutes and then 1,2,3 and 4 hours following the nasal challenge.

- **Blood draw (Day 1, 14 and 35):**

We will draw 10mL (about 2 teaspoons) of blood during the screening phase of the study. We will check your blood for different types of cell markers found in allergy driven cells and genes that are related to your ability to produce antioxidants. Your blood will also be measured for sulforaphane (a substance found in broccoli sprouts) levels. Total blood drawn during this study is 30mL (about 2 tablespoons) over the 5-week study period.

- **Questionnaire (Day 1, 14 and 35):**

You will be asked to complete a questionnaire called the Total Nasal Symptom Score (TNSS) where you will be asked to rate the symptoms of nasal congestion/postnasal drainage, itching, runny nose or sneezing. As mentioned above, you will complete this questionnaire when you undergo nasal challenges.

- **Peak Nasal Inspiratory Flow (Day 1, 14 and 35):**

You will also undergo a procedure called Peak Nasal Inspiratory Flow (PNIF) where you will be asked to exhale fully and quickly while having an airtight seal that covers your mouth and nose. After this is done, the technician will record the reading. You will repeat this study 2 more times.

- **Dietary Supplement: Avmacol® (Day 14 and 35):** We will ask you to take 4 tablets of a dietary supplement with your evening meal containing broccoli sprout extract (BSE). The supplement will be taken about the same time each day. We will ask you not to eat certain cruciferous vegetables (such as broccoli, kale, cauliflower, and brussel sprouts) for 3 days before visit 1, and while on the study. A complete list of these vegetables will be given to you by the study coordinator.

The study visit for Day 1 (screen) will last approximately 1 to 3 hours (based on how long the nasal challenge will take); study visits for Days 14 and 35 will last up to 5 hours. Please plan accordingly.

Subjects who participate in this study will be randomized to receive a three-week supply of one of the following regimens. Note, there is no active substance in placebo.

1. nasal corticosteroid
2. placebo nasal spray + dietary supplement containing BSE
3. nasal corticosteroid + dietary supplement containing BSE
4. placebo nasal spray

This will be determined randomly, in a process similar to flipping a coin. You will have an equal (25%) chance of being assigned to each study drug group. This is a double-blind study, which means that

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neither you nor the study doctor will know to which of these study drug groups you have been assigned. In case of an emergency, the study doctor can get this information. Visit 1 would take place once you have avoided consuming these vegetables for three days.

	Visit 1 Day 1	Visit 2 Day 14	Visit 3 Day 35
Informed Consent	X		
Medical History, Physical Exam (including weight and vitals)	X	X	X
Urine (WOCBP)	X		
Genetic Testing	X		
Blood Draw (SFN)	X	X	X
Allergy Skin test	X		
Nasal Exam	X	X	X
Nasal Challenge	X	X	X
Nasal Irrigation		X	X
Spirometry	X	X	X

**POSSIBLE RISKS OR DISCOMFORTS**

You may experience new symptoms or a change in your medical condition while taking part in this study. These symptoms or changes in your medical condition may or may not be due to study drugs/supplement being used.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study.

You will receive either nasal fluticasone or a nasal placebo spray. Placebo is a substance that looks like a drug but has no drug in it. If you receive placebo during the study, it is possible that your allergies may get worse. Please ask the study doctor or study staff if you have any questions about placebo.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

General Risk

There is a risk of experiencing allergy symptoms (itchy eyes and runny nose) if you stop taking antihistamines during the study.





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## POSSIBLE RISKS ASSOCIATED WITH STUDY PROCEDURES/TESTS

### Allergy skin testing:

There may be some mild redness and/or itching at the sites where the needle scratches the skin. This is expected and a normal part of this test when it is positive. If present, these symptoms will disappear over a period of less than one hour. There is an extremely small (less than 0.02%) chance you may get a severe allergic reaction to this test which may include hives (itchy rash) that may last several hours, "hay fever-like" symptoms such as sneezing or runny nose, chest tightness or even a drop in blood pressure. Qualified staff will perform skin testing and a board certified allergist will be available to address any complications. Medications such as epinephrine and Benadryl will be readily available.

### Nose Lavage:

The sensation of water in the nose may be mildly uncomfortable initially. There is a possibility of swallowing the saline, which has a salt-water taste but contains no other substances. Additional potential complications include inhaling the fluid, which is uncomfortable, but the amount of fluid is so small that there is no known possibility of any respiratory complication.

### Nasal Challenge:

Since we are placing grass pollen solution that you are allergic to in your nostril, you may experience "hay fever-like" symptoms (such as sneezing, nasal congestion, runny nose, or watery eyes). There is a very small chance that you could experience chest tightness or even a drop in blood pressure, known as "anaphylaxis". If this does occur, the test would be stopped and you would be treated. The reason why we perform a physical exam and have you perform spirometry (mentioned above) is to determine if you may be at slightly higher risk of developing anaphylaxis. If you are at risk to have such a reaction based on your exam and spirometry readings, you will not undergo the test.

### Dietary Supplement: Avmacol®

The reported risks associated with taking broccoli sprout extract are mild gastrointestinal discomfort (including mild stomach pain, mild diarrhea, soft, loose or watery stools), nausea, belching, bloating, or flatulence. If you find the flavor of broccoli sprout extract mixture is unpleasant, you may have discomfort associated with swallowing it. No other risks have been associated with broccoli with the ingestion of broccoli sprout ingestion and no serious adverse events have been observed or reported.

### Risks associated with blood sampling:

When giving blood you may feel dizzy or faint, or experience mild pain, bruising, irritation or redness at the site. In rare cases, you may get an infection.

### Loss of Confidentiality:

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.



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**Risk of Pregnancy:**

Since we do not know if the broccoli sprout extract mixture is safe for an embryo or fetus, females must not be pregnant while in the study. Females of childbearing potential will have a urine pregnancy test at the start of study. You must use an effective method of contraception throughout the study. Examples of acceptable effective methods are as follows: total abstinence (no intercourse), an intrauterine device (IUD), a double barrier method (such as a condom plus diaphragm with spermicide), a contraceptive implant, an oral contraceptive, or have a vasectomized partner with confirmed azoospermia (no sperm).

**If you become pregnant or suspect that you became pregnant while on the study, you must notify your research doctor immediately.** If you are scheduled to participate, you will be immediately taken out of the study. If you are already taking study drug, you will be immediately taken off study drug and continue participation through follow-up visits. The research doctor or a member of the research team may ask for information about the pregnancy outcome (limited to "live birth, miscarriage or termination of pregnancy").

**POTENTIAL BENEFITS**

We cannot promise that you will get any benefits from taking part in this research study. However, taking part in this study may or may not make your allergic rhinitis better, and may or may not have a direct benefit to you. You may get placebo, which is a substance that looks like a drug but has no drug in it.

The research may increase our understanding of the healthful effects of vegetables such as broccoli sprouts on the respiratory and immune system. This information may be important in improving nasal health for people with allergies and asthma, and for developing ways to protect people from the harmful effects of air pollution.

**ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH**

You will continue to get regular care from your own regular doctor(s) if you choose not to participate in this study. You can get fluticasone without participating in the study. You might decide to take part in another study instead. Talk with your study doctor about your choices. In addition, you may discuss your options with your regular health care provider.

**CONFIDENTIALITY**

Your data will be combined with data from other people taking part in this study. We will write medical articles about the combined data we have gathered. Any talks or papers about this study will not identify you.

We will not share your records or identify you unless we have to by law. There are times when we have to show your records to other people. For example, someone from the State or Federal





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Regulatory Agencies, the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the Government Accountability Office (GAO), the VA Office of Research Oversight (ORO), the Institutional Review Board (IRB) – VAGLAHS and any of its delegated sub commissions, our local Research and Development Committee, the Research Compliance Officer and other study monitors may look at portions of records that identify you.

Your participation in this study is entirely confidential and will not affect any medical care to which you are otherwise entitled.

In the event your study doctor is unable to locate you (e.g. after making 3 phone call attempts and sending a certified letter) for the limited purpose of collecting necessary follow-up data, you authorize your study doctor to contact your private physician/General practitioner for the sole purpose of updating your study doctor with your current contact information.

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. While the VA and the researchers on the team will do everything to prevent any loss of information, in the event that there is a breach of information, you will be contacted by the VA directly.

All records containing personal information, research data, and related records will be stored in locked files at a VA Room at Building 500. All data that will be collected will be assigned with a personal identification code to protect personal privacy. It will be accessible only by members of the research team named above. The required records, including the investigator's research records, must be retained for 6 years after the study is closed by the National Archives and Records Administration (NARA.gov) guidance as implemented by VHA Records Schedule (DAA-0015-2015-0004). These records may be retained longer if required by other Federal regulations.

We will keep confidential all research records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, someone from the Food and Drug Administration, the Office of Human

Research Protections, the Government Accounting Office, the VA Office of Research Oversight, our Institutional Review Board, our Data and Safety Monitoring Board and the Research Compliance Office may look at or copy portions of records that identify you, including your medical record; the sponsor and its authorized agents may look at, but not copy, portions of the records that identify you, including your medical record. In addition, please note that VA policy requires that a note be written in your medical record concerning the consent process and your enrollment in this study. Thus non-research VA staff will have access to that information in the course of clinical care.



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In addition, in accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that acts of child abuse or elder abuse may have occurred.

We may write about the combined information we have gathered, however, any presentations or publications from this information will not identify you.

At the end of this form you will be asked for your permission to allow the VA to share your Personal Health Information with the research team for use in this study. Your separate signature on that part of the consent form will reflect your official authorization.

## **COSTS TO PARTICIPANTS AND PAYMENT**

### **Costs to Participants:**

You will not be charged for any treatments or procedures that are part of this research study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

## **PAYMENT OFFERED FOR PARTICIPATION**

You will be paid up to \$300 if you complete the entire study. If you do not complete the study, your payments will be pro-rated as follows: Twenty dollars (\$20.00) will be paid to participants who complete up to the skin test procedure at visit 1, and do not meet study qualifications (skin test results determine that you not allergic to grass) to continue participation in the study. Forty-five dollars (\$45.00) will be paid to participants who meet study qualifications and complete visit 1. Ninety dollars (\$90.00) will be paid to participants who complete visit 2. Ninety dollars (\$90.00) will be paid to participants who complete visit 3. Additionally, those participants who will comply with study protocol and complete all three study visits will receive the completion of study payment in amount of \$75 at the end of the study. These payments are to cover your travel expenses and for the time and effort you have expended. You will be paid in cash at the completion of your study visit. If you decide to withdraw or you are withdrawn by the study doctor, your payment will be prorated for the visits you completed.

In addition, it is VA policy that the amount you receive from this study is more than \$550.00 it will be reported to the Internal Revenue Service (IRS) and may be considered taxable income. This will be reported using a 1099 (Miscellaneous Income) form. This form will be issued to you and a copy mailed to the IRS.

As part of the study, you will receive study drug and all the study tests and procedures at no cost to you.



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You and the VA or your insurance company/the National Health Service will continue to pay for your regular health care.

### MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. However, no plans or funds for additional compensation have been set aside. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Zhaoping Li, MD, PhD at 310-268-3528

Dr. Joseph Yusin, MD at 310-478-3711 x 40230 and,

AFTER HOURS:

Dr. Zhaoping Li, MD, PhD at 310-261-5024

Emergency and ongoing medical treatment will be provided as needed.

### YOUR RIGHT TO TERMINATE PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

At the end of the study, the study staff will contact you, your family or your friends to ask about your health status even if you withdraw from the study. If you withdraw from the study and revoke your Authorization to Use and Disclose your Protected Health Information, the study doctor will not call you at the end of the study and your information will no longer be used by the study doctor and staff for this study, except to the extent the parties to the research have already taken action or need the information to complete analysis and reports for this research.



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The sponsor will still use the study information that was collected before you withdrew from the study. If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.

## RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

The investigator may withdraw you from participating in this research if circumstances arise that warrant doing so. The study doctor or the sponsor can stop your participation at any time without your consent for reasons such as:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons, including competitive enrollment - the target number of subjects has enrolled.

New information may become available that might affect your choice to take the study drug or your willingness to continue in the trial. This new information may include safety issues with the study drug. Such information will be shared with and discussed with you.

Should you become ill during the research, you may have to withdraw, even if you would prefer to continue. The investigator Zhaoping, Li, M.D. or Dr. Joseph Yusin, will make the decision and inform you if your continued participation is not possible. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

## What happens if I do not want to stay in the study?

You should discuss your decision with your study doctor. It is important for the study that you provide follow-up information on your health status until the end of the study. If you stop participating in the study (that is you stop taking study drug and you decide not to attend clinic or allow us to contact you by telephone) information about your overall health will continue to be collected until the end of the study.

Any information that is available to the public and allowed by local law and is important for the study, including whether you are alive, may be used, even if you stop participating in the study.

If you have provided blood (or urine, if you are a woman of child bearing potential) samples, you may withdraw your consent for these to be used at any time. Your samples will be destroyed at that time. However, all the data and samples collected before you left the study will still be used for the study.



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You may ask that your samples be destroyed but any data already collected about your samples will be used for the study.

## PERSONS TO CONTACT ABOUT THIS STUDY

In the event that you have a question about the research or experience a research related injury or adverse reaction, please immediately contact one of the investigators on this study: Dr. Zhaoping Li at 310-261-5024 or Dr. Joseph Yusin at 310-478-3711 x40230.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Greater Los Angeles Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Greater Los Angeles IRB toll free at 1-310-268-4437 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

## SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available about the BSE that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

## GENETIC INFORMATION IN YOUR SAMPLE: POSSIBLE LIMITS TO INDIVIDUAL CONFIDENTIALITY

Every tissue or fluid sample contains genetic information. In this study we are identifying the genetic variation of an antioxidant enzyme that has been found to modify the effect of broccoli sprouts on allergic rhinitis. Every precaution will be taken to maintain your confidentiality now and in the future and to safeguard your genetic material.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggesting different parentage is obtained during research. In this study we do not plan to determine parentage.



**Study Title:** "Effects of Broccoli Sprout Extract on Allergic Rhinitis"

**Principal Investigator:** Zhaoping Li, MD, PhD

Phone: 310-268-3528

**Co-Principal Investigator:** Joseph Yusin, MD

Phone: 310-478-3711 x40230

Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information.

### AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms \_\_\_\_\_ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

**I agree to participate in this research study as has been explained in this document.**

_____ Participant's Name	_____ Participant's Signature	_____ Date
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**I agree to participate in the GENETICS part of this research study as has been explained in this document.**

_____ Participant's Name	_____ Participant's Signature	_____ Date
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_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date
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## RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.